UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

- Contains Confidential Business Information -

DP BARCODE No.: 445793, 446300; **FILE SYMBOL No.:** 2749-560; **PRODUCT NAME:** Bifenthrin Technical MUP; **DECISION No.:** 538028; **PC Code(s):** 128825; **ACTION CODE:** R351 **FOOD Use:** YES

DATE OUT: August 21, 2018

SUBJECT: Product Chemistry Review for *"Bifenthrin Technical MUP"*
-Amendment to Add New Unregistered Source of the Active Ingredient (ALT #3)

FROM: María I. Rodríguez, Chemist
Product Chemistry Reviewer
CITAB/RD (7505P)

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
CITAB/RD (7505P)

TO: Julie Breeden-Alemi/Beth Fertich, RM#4
IV#1B/RD (7505P)

INTRODUCTION:

The CITAB (Chemistry) has been asked to determine the acceptability of supporting Product Chemistry data submitted with this application.

Registrant: Product & Regulatory Associates, L.L.C., On Behalf of Aceto Agricultural Chemical Corp.

Application Date: December 16, 2016

Proposed Product: Intended for use in formulating insecticides only for the uses indicated on the label

Supporting Data: Alternate (ALT) #3 CSF, MRID Nos 504848-05, -06, -09, -10, -11, -12, 505411-01 and other studies cited in Data Matrix dated 12-22-2017

45/90-Day Completeness Screen: NO Screen Due to Time Constraints

NOTE: Refer to the "*Confidential Appendix*" (Pages 6 - 10) for information on the unregistered technical

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SUMMARY OF FINDINGS:

1. Name(s) of Active Ingredient(s): Bifenthrin (98.46%)

2. Has the registrant claimed substantial similarity to a registered product? [ ] Yes; [X] No

3. All of the source materials of the active ingredients are derived from registered sources: [ ] Yes; [X] No

4. All inert ingredients have been screened by CITAB (Inerts) and found to be approved for the proposed labeled use(s): [ ] Yes; [X] No
   -For future submissions, please ensure all the CSFs are screened by CITAB (Inerts). Otherwise, the submission will be returned unreviewed. This applies even to "Manufacture Use Products" (MUPs).

5. Confidential Statement(s) of Formula (CSFs):

   [ ] Proposed Basic CSF: Dated: NA; Revised: NA
   [X] Proposed Alternate #3 CSF: Dated: 02-14-2018; Revised: NA

   -NOTE: Current Basic CSF is dated 05-28-2010/accepted 06-15-2011 (SMathur)

6. Product label:

   -NOTE: OPPIN/PPLS Database – Last accepted label is dated 10-29-2013

   a. Ingredient statement: Nominal concentration (NC) of AIs listed on CSF concur with product label (PR Notice 91-2): [X] Yes; [ ] No

      Is the sub statement in compliance with PR Notice 97-6 (inert ingredients vs other ingredients)? [X] Yes; [ ] No

      Metallic equivalent: [ ] Yes; [ ] No; [X] NA
      Soluble arsenic: [ ] Yes; [ ] No; [X] NA
      Isomeric ratios: [X] Yes; [ ] No; [ ] NA
      -NOTE on Label: *Cis isomers 97% minimum, trans isomers 3% minimum."*
      Acid Equivalent: [ ] Yes; [ ] No; [X] NA

   b. Health related sub statements: Product contains?

      Petroleum distillate at > 10%: [ ] Yes; [ ] No; [X] NA
      Methanol at > 4%: [ ] Yes; [ ] No; [X] NA
      Sodium nitrate/Sodium Nitrite: [ ] Yes; [ ] No; [X] NA

   c. Physical-chemical hazard statement: Product label requires a statement *per* 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? [X] Yes; [X] No

      -NOTE: The current label has the following statements under the "*Physical-Chemical Hazards*" section: "*Do not use or store near heat or open flame.*"

      Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [ ] Yes; [ ] No; [X] NA

   d. Label requires an additional Storage and Disposal statement: [ ] Yes; [X] No

7. Group A: Product Chemistry Data – Product Identity, Composition, and Analysis

-Only data submitted with this submission is being reviewed at this time.

Guideline Number	Study Title		Data Submitted		CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
			Yes	No		
830.1550	Product Identity & Composition		X		A	504848-05
830.1600	Description of materials used to produce the product		X		A	504848-05 (MSDSs Provided)
830.1620	Description of the production process		X		A	504848-05
830.1650	Description of formulation process		-----	-----	NA	NA Data Matrix
830.1670	Discussion on the formation of impurities		X		A	504848-05 504848-06
830.1700	Preliminary analysis		X		A	504848-06
830.1750	Certified limits (158.350)	Standard certified limits	X		A	504848-05 ALT #3 CSF (02-14-2018)
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	504848-06 Technical & Impurities HPLC – UV - DAD HPLC - NMR (Validated)

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable; I = In Progress; U = Upgradeable

8. Group B: Product Chemistry Data – Physical and Chemical Characteristics

Guideline Number	Study Title	Value or Qualitative Description	CITAB's Assessment	MRID Number
830.6302	Color	White	A	504848-09
830.6303	Physical State	Solid	A	504848-09
830.6304	Odor	Faintly aromatic	A	504848-09
830.6313	Stability to Normal & Elevated Temperatures, Metal, and Metal Ions	Waiver requested/granted – Stable & Compatible	W	504848-09
830.6314	Oxidation/reduction	Waiver requested/granted – Does not contain an oxidizing or reducing agent or function groups of significant reactivity	W	504848-09
830.6315	Flammability	NA - Solid	NA	504848-09
830.6316	Explodability	Waiver requested/granted –Does not contain any structurally reactive components; not explosive	W	504848-09
830.6317	Storage stability	Stable @ 54 °C for 2 weeks	A	504848-09
830.6319	Miscibility	Waiver requested/granted – Not an EC	W	504848-09
830.6320	Corrosion characteristics	Stable @ 54 °C for 2 weeks	A	504848-09
830.6321	Dielectric Breakdown Voltage	Waiver requested/granted – Not labeled for use in and around outlets	W	504848-09
830.7000	pH	NA – Solid; not water soluble nor designed to be dispersed in water	NA	504848-09
830.7050	UV/Visible Absorption	Neutral, #1: 204.65 nm, 1.3789 AU; #2 201.31 nm, 1.3284 AU Acidic, 204.06 nm, 1.4882 AU Basic, 217.54 nm, 0.9346 AU	A	505411-01
830.7100	Viscosity	NA – No data submitted	NA	504848-09
830.7200 830.7220	Melting Point Boiling Point	MP = 65 – 71.6 °C	A	504848-09
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.398 to 0.794 g/mL Loose to Tapped	A	504848-09
830.7370	Dissociation Constant in Water	Waiver requested/granted	W	504848-09
830.7520	Particle Size & Related	NA – No data submitted	NA	504848-09
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Log Pow 7.265 @ pH 7.03, 25 °C	A	504848-10
830.7840 830.7860	Solubility – Water Solubility - Organic Solvents	@ 20.1 °C, pH 5.54: Water < 1.895 x 10^{-3} mg·L^{-1} (LOD) Acetone 571.646 g·L^{-1} @ 20.0 °C: n-Hexane 182.355 g·L^{-1}	A	504848-11
830.7950	Vapor Pressure	4.9247 x 10^{-7} Pa (Extrapolated @ 20 °C)	A	504848-12

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable; I = In Progress; U = Upgradeable

CONCLUSIONS:

CITAB has reviewed the Product Chemistry data submitted and has concluded that:

A. Substantial Similarity to the Cited Product from Product Chemistry View Point
[ ] Similar to cited product
[ ] Not similar to cited product
[ ] Identical to the cited product in chemical composition
[ ] Not identical
[X] Not applicable

B. **Confidential Statement(s) of Formula**
1. Basic CSF
[ ] Acceptable
[ ] Not Acceptable
[X] Not Applicable

2. Alternate #3 CSF (dated 02-14-2018)
[X] Acceptable
[ ] Not Acceptable
[ ] Not Applicable

C. Group A Product Chemistry Data – Data Submitted & Cited
[X] Acceptable
[ ] Not acceptable
[ ] Acceptable with the exception of Guideline(s): *cite Guideline(s)*
[ ] Not required
[ ] Data cited

D. Group B Product Chemistry Data – Data Submitted & Cited
[X] Acceptable
[ ] Not acceptable
[ ] Acceptable with the exception of Guideline(s): *cite Guideline(s)*
[ ] Not required
[ ] Data cited

E. Product Label/Draft Label
Recommendations – Yes [ ]; No [X]

-No additional recommendations at this time.

CONFIDENTIAL APPENDIX

Information as provided by the Registrant.

830.1550: Product Identity & Composition:

Common Name: Bifenthrin

Chemical Name:

CAS

(2-Methyl[1,1'-biphenyl]-3-yl)methyl(1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethylcyclopropanecarboxylate

IUPAC

2-Methylbiphenyl-3-ylmethyl(1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate
or
2-Methylbiphenyl-3-ylmethyl(1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

CAS No.: 82657-04-03

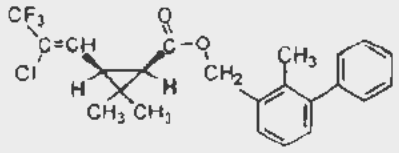
PC Code No.: 1218825

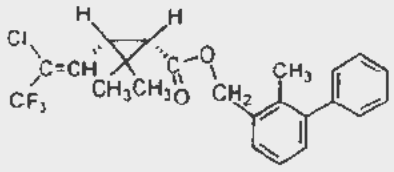
Empirical Formula: $C_{23}H_{22}ClF_3O_2$

Molecular Weight: 422.9 g/mol

Structural Formula:

(Z)-(1*R*)-*cis*-





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Pages 7-10*Manufacturing process information may be entitled to confidential treatment*